

III. Amendments to the Drawings

Two replacement sheets of drawings (sheets 1/9 and 9/9) including changes to original Figures 1 and 9 are attached, along with an annotated copy identifying changes made. Specifically, a bracket was added to the exploded view of Figure 1 to identify each component thereof as part of the single view; and the six views originally presented as single Figure 9 have been relabeled Figures 9A through 9F.

IV. Remarks

Claims 1-18 are pending in this application. Of these, claims 1-3 and 6-18 stand provisionally elected without traverse (claims 1 and 2 having been deemed generic, and claims 3 and 6-18 being directed to the provisionally-elected species that includes an opening means comprising a cutting member protruding from the recited connector device), and claims 4 and 5 stand provisionally withdrawn as directed to a non-elected species. Additionally, claims 1-3 and 6-18 stand rejected as either anticipated by, or obvious in view of, several applied prior art references. The Drawings stand objected-to for allegedly failing to show "valve means," "dosing means," and "pump unit" as recited in pending claims 11, 16, and 14, respectively, while the title of the application stands objected-to, both for containing a typographical error and for allegedly not being "clearly indicative of the invention to which the claims are directed."

By this paper, Applicants are canceling without prejudice claims 1, 6, and 9; rewriting claims 2 and 7 into independent form by including the limitations of former base claim 1 and, in the case of claim 7, formerly-intervening claim 6; rewriting claim 13, and presenting new claim 19, to eliminate a multiple-dependency inadvertently remaining in claim 13; and amending claims 8, 10, 14, and 15 to provide proper dependencies. New claims 20-23 have also been added, to more particularly point out and distinctly claim that which Applicant regards as the invention, 35 U.S.C. §112, second paragraph. Applicants have also amended the title of the application in the manner suggested by the Examiner, as well as amended Figures 1 and 9 and the correlative text at specification pages 8 and 21 to better conform to Rule 84. No new matter has been added to the application by virtue of these amendments.

Applicants note that pending claims 2, 3, 7, 8, and 10-18, as well as new claims 19-23, are each readable on the provisionally elected species.

Reconsideration and further examination of claims 2, 3, 7, 8, and 10-23 are respectfully requested.

THE OBJECTIONS TO THE DRAWINGS

Turning to the substantive objections and rejections as set forth in the Detailed Action, the Drawings stand objected-to for failing to show certain features recited in the claims, namely, the “valve means” of claim 11, the “dosing means” of claim 16, and the “pump set” of claim 14. However, Applicants respectfully submit that each of these features are shown in at least one of the original Figures:

- ♦ the “valve means” is incorporated in “venting means 7” as shown in Figures 2 and 3 (see, also, the accompanying text at specification page 13, lines 28-32; specification page 15, lines 7-11);
- ♦ the “dosing means” is shown as roller clamp 70 in each of Figures 9A-9F (see, also, the accompanying text at specification page 21, lines 10-11); and
- ♦ the “pump set” is shown as “pumping unit 60” in Figures 9A and 9D (see, also, the accompanying text at specification page 21, lines 13-15).

In view of the foregoing, Applicants respectfully request the withdrawal of the objections to the Drawings.

THE OBJECTION TO THE SPECIFICATION (TITLE)

As noted above, by this paper, Applicants have amended the title in the manner suggested by the Examiner. Applicants respectfully submit that the objection to the title has thus been obviated by amendment.

A PRELIMINARY REMARK AS TO CLAIMS SCOPE

Independent claims 2 and 7, as amended, continue to recite many of their respective elements in their original, “means-plus-function” form to thereby invoke 35 U.S.C. §112, sixth paragraph. See, e.g., MPEP §2181. For example, claims 2 and 7 each recite a “means adapted to fit to the enteral administration set,” with the corresponding structure disclosed in the specification, for example, at page 2, lines 25-33, as including a rigid tube part for attachment of a feeding line of the enteral administration as by a frictional fit and/or with an adhesive (“glue”). Claims 2 and 7 each also recite a “means adapted to fit to the laminated paper packaging system,” whose corresponding structure is respectively disclosed in the specification, for example, at page 2, line 33 to page 3, line 16, as including either a threaded element on the connector device adapted to threadably engage a complementary threaded “frame-like member” or “neck” defined on the laminated paper packaging system (e.g., the Tetra Brik®

container); and, for example, at page 4, lines 14-18, as including a spike for penetrating into the interior of the laminated paper packaging system, as well as an "attachment means for fixedly attaching the connector device to the laminated paper packaging system." This latter-referenced "attachment means," also recited in claim 7, corresponds either to a single "rim" or flange on the spike having a pressure-sensitive adhesive on one side with which to glue the connector device to the penetrated surface of the packaging system, as described, for example, at page 4, lines 25-34; or to a pair of parallel-spaced "rims" on the spike, only one of which is "made from a flexible material" to permit its installation through the penetrated surface of the packaging system, whereby the penetrated surface "is fixedly enclosed between the two axially spaced rims," as described, for example, at page 5, lines 4-17.

Similarly, the last clause of claim 2 continues to invoke 35 U.S.C. §112, sixth paragraph, by reciting a "means for opening of the laminated paper packaging system upon screwing the connector device onto the frame-like member of the laminated paper packaging system." The structure generally corresponding to the "means for opening" is described, for example, at page 3, line 18 through page 4, line 3, either as a "cutting member protruding from the connector device" that is "intended to cut the laminated paper packaging system upon screwing the connector device onto the frame-like member of the laminated paper packaging system" (emphasis added); or the combination of a "triggering member" on the connector device that "acts upon a leverage system" on the packaging system's frame-like member, which in turn operates to cut the surface of the packaging system.

By its own terms, claim 2 is limited to the first species of the disclosed "means for opening" (wherein "opening" occurs "upon" screwing" the connector device onto the packaging system). And, as explicitly described at specification page 12, lines 1-3:

The length, position and number of cutting means 13, e.g., projecting means, may be adapted to cut laminated paper packaging system 4 when connector device is connected, e.g. sealably connected, thereto, e.g. screwed onto frame-like member 11.

(Emphasis added.) Thus, properly construed in view of the disclosure under the mandate of 35 U.S.C. §112, sixth paragraph, the recited "means for opening ... upon screwing" means a cutting member that begins to cut the surface of the packaging system only after the mating threaded portions of the recited "means adapted to fit..." have begun to engage each other (as one can only "screw" together threaded components that have at least initially engaged one another). Applicants note that this construction is fully consistent other claims (for example, original claim 3 which further recites "cutting ... upon screwing"), and with the stated objective of

preserving the sterility of the composition within the laminated paper packaging system (see, e.g., specification page 4, lines 4-23).

THE CLAIMS REJECTIONS

Turning to the substantive rejections presented in the Office action mailed September 8, 2006, claims 1, 10, and 12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,895,275 ("Quinn"). Claim 1 has been cancelled from the application, and Applicants respectfully traverse the rejection with respect to claims 10 and 12, each of which now depends either directly or indirectly from independent claim 2.

Quinn teaches a "dispensing spike for penetrable pre-filled shape retentive containers" in which the pointed end 24,26 of an inlet arm 22 is used to puncture and penetrate a surface of the container 10 (col. 3, lines 30-37). Quinn expressly states that the length of the inlet arm 22 "is selected to coincide with the volumetric size of container 10 so that terminal end 24 is positioned at or near the bottom of the container" to allow the arm to draw fluid "from the bottom of container 10" (col. 3, lines 40-44), while a large flange 36 on the upper portion of the arm 22 "limits the extent that arm 22 may be inserted into the container and prevents inadvertent submersion of vent inlet 34 into the fluid in container 10" (col. 3, lines 61-64).

Thus, after "puncturing" the container with the arm's pointed end, Quinn simply relies upon the weight of the dispensing spike to urge the inlet arm 22 down into the container, preferably to the point at which the flange 36 engages the punctured top surface of the laminated paper packaging system. As such, Quinn fails to teach any "means adapted to fit to the laminated paper packaging system" recited in independent claim 2, which as noted above is properly construed to require a threaded engagement between the dispenser and the packaging system, let alone the further limitation of claim 2 that "the connector device further comprises means for opening ... upon screwing the connector device onto the frame-like member" of the packaging system.

For at least the foregoing reasons, Applicants respectfully submit that independent claim 2, as well as its dependent claims 10 and 12, are neither anticipated by, nor obvious in view of, Quinn.

Claims 1-3, 6-9, 13, 17, and 18 stand rejected under 35 U.S.C. §§102(b) and 102(e) as being anticipated by Canadian Patent No. 2,432,623 and its US counterpart, pre-grant publication no. US 2004/0104246A1, respectively (collectively referred to as "Kawaguchi," with citations made only to the pre-grant published application for clarity). Claims 1, 6, and 9 have been cancelled from this application, and Applicants respectfully traverse the rejections with respect to claims 2, 3, 7, 8, 13, 17, and 18.

Kawaguchi teaches an adapter for a beverage pack in which an elastic “fixing member” having a through-hole is first secured to the beverage pack such that the through-hole “is aligned with the opening in the beverage pack” (para. 0010), whereupon the pointed “distal end” of a generally tubular adapter 12 is inserted into the beverage pack through the through-hole and the opening, whereupon the elastic fixing member elastically deforms about the adapter to achieve a seal about the adapter (para. 0010). Kawaguchi teaches several variations of the adapter, some of which include peripheral features which engage the flexible fixing member over its nominal thickness to achieve an improved seal and prevent unintended pull-out, such as a locking ridge SR as seen in Figure 2, and peripheral threads SS as seen in Figure 4. In each embodiment, though, the adapter body is said to be “formed by injection molding from a semi-hard material such as polypropylene, polyethylene, or another polyolefin, or polycarbonate, polystyrene, or the like” (para. 0029). A further variation, shown in Figure 6, includes a flexible, tubular “linking member 114” having a wide radial flange on one end that is secured by an adhesive to the top of the beverage pack, and a narrow radial flange on the other end that cooperates with a rigid, encompassing “annular member” or collar 112b on the adapter body 112 to thereby lock the adapter 110 within the linking member 114. Significantly, Kawaguchi emphasizes that, when attaching the adapter 10, “the pointed end 12a punctures the film 21 [on the beverage pack 20] and goes into the opening 21, but the flange 12c serves as a stopper so that only the pointed end 12a enters the beverage pack 20” (para. 0040) – in other words, the pointed end has punctured the film on the beverage pack well in advance of the engagement of any flange 12c or other peripheral sealing feature, such as the sealing ridge SR or male threads SS, with the fixing member 14 atop the beverage pack.

Thus, Kawaguchi teaches only flexible elements secured to the top of the beverage package (the elastic “fixing member 14” shown in Figures 1-5, and the elastic “linking member 114” of Figure 6), and only teaches the use of threads to improve the “elastic fit” achieved between the adapter body and the relatively-thin elastic “fixing member 14.” Simply stated, Kawaguchi fails to teach a connector device that includes “means adapted to fit to the laminated paper packaging system ... compris[ing] an internally threaded portion adapted to be screwed onto a corresponding outwardly threaded portion of a frame-like member of the laminated paper packaging system,” as recited in independent claim 2, let alone that claim’s further recited “means for opening ... upon screwing the connector device onto the frame-like member.” And, because Kawaguchi teaches gluing its elastic fixing member or elastic linking member to the top of the beverage pack before elastically capturing the adapter body within the fixing member’s through-hole or the linking member’s axial bore, Kawaguchi fails to teach a connector having a rim or flange, facing toward the packaging system, on which an adhesive layer has been provided for fixedly attaching the connector device to the packaging system, as recited in independent claim 7. Still further, because Kawaguchi employs a “semi-hard material” for its

adapter body when relying upon the elastic fixing member adhered to the top of the beverage pack to cooperatively achieve a seal, Kawaguchi not only fails to teach a pair of axially-spaced rims or flanges as recited in dependent claim 8, wherein the one located nearer the point of the spike is made from a flexible material and the one located farther from the point of the spike is made from a rigid material, but Kawaguchi must necessarily be viewed as teaching away from such a construction.

For at least the foregoing reasons, Applicants respectfully submit that independent claims 2, 7, and 8, , as well as its dependent claims 13, 17, and 18, are neither anticipated by, nor obvious in view of, Kawaguchi.

Claim 11 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Quinn in view of U.S. Patent No. 4,888,008 ("D'Alo").

While the Examiner is correct in identifying D'Alo as teaching a one-way valve for venting air into a container from which fluid is being drawn, D'Alo does nothing to cure the deficiencies of Quinn as described above with respect to independent claim 2, from which claim 11 directly depends. Accordingly, for at least those reasons, Applicants respectfully submit that claim 11 is patentable over the art of record in this application.

Claims 14 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi in view of Quinn and U.S. Patent No. 5,993,422 ("Schafer"), while claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi in view of Quinn and U.S. Patent No. 3,001,525 ("Hendricks").

Once again, while the Examiner is correct in identifying Quinn as using a laminated paper packaging system for enteral administration, Schafer as disclosing use of a pump, and Hendricks as teaching parenteral equipment that includes an intermediate bag for mixing solutions, Quinn, Schafer, and Hendricks, taken either singly or in combination, do not cure the deficiencies of Kawaguchi as described above with respect to independent claim 2, from which claims 14-16 each indirectly depends. Accordingly, for at least those reasons, Applicants respectfully submit that claims 14-16 are patentable over the art of record in this application.

From the foregoing, Applicants respectfully submit that claims 2, 3, 7, 8, and 10-23 as amended are patentable over the prior art of record in this application, and a notice of allowability with respect to claims 2, 3, 7, 8, and 10-23 is courteously solicited.

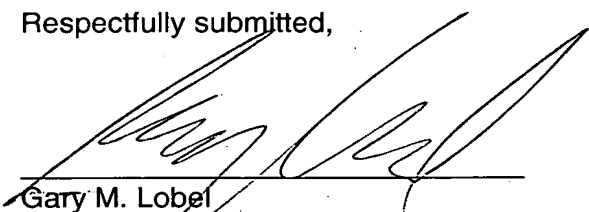
FEE DETERMINATION AND DEPOSIT ACCOUNT AUTHORIZATION

Applicants have calculated a fee of \$450.00 to be due under 37 C.F.R. §1.17(a)(2), for a two-month extension of the shortened-statutory period for response to the outstanding Office

action. As noted in the Transmittal to which this paper is attached, Applicants authorize the Director to charge this fee, and to charge any fee deficiency and credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,

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Attachments: Two Replacement Sheet(s) of Drawings